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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,053	02/21/2002	Kenneth Houston	DR-332J	6756

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EXAMINER
BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
1744	

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260 Bear Hill Road
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DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,053	HOUSTON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005 and 16 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 21-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 6/24/05 and 11/16/05 have been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 19 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al.(Biosensors and Bioelectronics, Vol. 13) in view of Karube et al.(EP 0 215 669).

The reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody) for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and "2. Experimental" section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a "dip holder with a plug". This disclosure is interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

Claims 19 and 21 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

With respect to claims 22, 24-33 and 35, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the "Experiment" and "Results and discussion" sections). As shown in Figures 3-5, the detection circuit is configured to "continuously" and "instantaneously" detect a shift in frequency due to the attached pathogen.

With respect to claim 23, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 33, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

Claim 34 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a

cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

With respect to claim 36, the seal or plug is provided at the top of the vessel.

With respect to claim 37, while the reference of Park et al. discloses that the sensor is communicated within the vessel through the top, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to communicate the sensor through a side or bottom of the vessel while still providing the required function of communicating the biosensor with the interior of the vessel while maintaining the vessel in a sealed condition. Note mere rearrangement of parts is not a patentable distinction (See In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

6. Claims 19 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al.(Biosensors and Bioelectronics, Vol. 13) in view of Qu et al.(Analyticaa Chimica) or He et al.(Talanta) taken further in view of view Karube et al.(EP 0 215 669).

With respect to claim 19, the reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody) for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and "2. Experimental" section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a "dip holder with a plug". This disclosure is

interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

If the disclosure is interpreted that the recited plug is an electrical plug and does not seal the vessel, the references of Qu et al. and He et al. are cited as prior art that discloses communicating a quartz crystal sensor within a culture vessel wherein a seal is provided between the vessel and an electrical connection (See Figure 1 of Qu et al. and Figure 1 of He et al.).

In view of either of these disclosures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to communicate the biosensor of the device of the primary reference using a vessel and sensor configuration of either of the references of Qu et al. or He et al. for the known and expected result for providing a means recognized in the art for communicating a quartz crystal sensor with the liquid contents of a culture vessel while protecting the contents of the vessel from contamination form the surrounding environment which is known in the art for ensuring the integrity of the test system.

Claims 19 and 21 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and

expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

With respect to claims 22, 24-33 and 35, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the "Experiment" and "Results and discussion" sections). As shown in Figures 3-5, the detection circuit is configured to "continuously" and "instantaneously" detect a shift in frequency due to the attached pathogen.

With respect to claim 23, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 33, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

With respect to claim 36, the seal or plug is provided at the top of the vessel.

Claim 34 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

With respect to claim 37, while the reference of Park et al. discloses that the sensor is communicated within the vessel through the top, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to communicate the sensor through a side or bottom of the vessel while still providing the required function of communicating the biosensor with the interior of the vessel while maintaining the vessel in a sealed condition. Note mere rearrangement of parts is not a patentable distinction (See In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

7. Claims 19 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al.(Biosensors and Bioelectronics, Vol. 13) in view of Qu et al.(Analyticaa Chimica) or He et al.(Talanta) and any of Kouznetsov et al.(US 6,250,140); Oyama et al.(US 6,544,478) or ICM (Liquid Flow cells) taken further in view of view Karube et al.(EP 0 215 669).

With respect to claim 19, the reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody) for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and "2. Experimental" section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a "dip holder with a plug". This disclosure is interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

If the disclosure is interpreted that the recited plug is an electrical plug and does not seal the vessel, the references of Qu et al. and He et al. are cited as prior art that discloses communicating a quartz crystal sensor within a culture vessel wherein a seal is provided between the vessel and an electrical connection (See Figure 1 of Qu et al. and Figure 1 of He et al.).

In view of either of these disclosures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to communicate the biosensor of the device of the primary reference using a vessel and sensor configuration of either of the references of Qu et al. or He et al. for the known and expected result for providing a means recognized in the art for communicating a quartz crystal sensor with the liquid contents of a culture vessel while protecting the contents of the vessel from contamination form the surrounding environment which is known in the art for ensuring the integrity of the test system.

If it is determined that either of the references of Qu et al. or He et al. do not provide a "seal" between the vessel and the electrical connection for sealing the vessel, the references of Kouznetsov et al.(US 6,250,140); Oyama et al.(US 6,544,478) or ICM (Liquid Flow cells) all disclose that it is conventional in the art to provide a seal between a QCM and the electrical connection between the QCM and the detection circuit (See Figure 1 of Kouznetsov et al.; Figure 17 of Oyama et al. and Flow Cells and Static Cell of ICM).

In view of these additional teachings, if the references of Qu et al. and He et al. do not inherently provide a seal as required of claim 19, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the systems of the modified primary references with "seals" between the QCM and electrical connection with respect to the vessel for the known and expected result of providing the required electrical connection between the QCM

exposed to the vessel interior while allowing the QCM to be connected to an external detection circuit while preventing the escape or contamination of the contents of the vessel during the testing process.

Claims 19 and 21 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

With respect to claims 22, 24-33 and 35, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the "Experiment" and "Results and discussion" sections). As shown in Figures 3-5, the detection circuit is configured to "continuously" and "instantaneously" detect a shift in frequency due to the attached pathogen.

With respect to claim 23, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 33, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

With respect to claim 36, the seal or plug is provided at the top of the vessel.

Claim 34 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

With respect to claim 37, while the reference of Park et al. discloses that the sensor is communicated within the vessel through the top, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to communicate the sensor through a side or bottom of the vessel while still providing the required function of communicating the biosensor with the interior of the vessel while maintaining the vessel in a sealed condition. Note mere rearrangement of parts is not a patentable distinction (See In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Response to Arguments

8. With respect to the rejection of claim 19 under 35 USC 102 over the reference of Park et al., Applicants' amendments to claim 19 and associated comments (See pages 7-9 of the response filed 6/24/05) are persuasive to overcome this rejection.

With respect to applicants' comments that the "plug" of Park is an electrical connector and not a seal for the vessel. Applicants' conclusion is based on the disclosure of the process of "dipping" the implies momentary or partial immersion.

In response, it is not clear how Applicants can positively conclude that the reference to a "plug" is an electrical connector. The disclosure is silent as to "plugging" the connector to the driving monitoring system. Applicants' discussion of "dipping" does not preclude the use of a plug that holds the sensor and dips the sensor within the vessel while also sealing the vessel from contamination during use. Even if the sensor can be reused, the sensor is maintained in contact with the interior of the culture vessel during the detection method. Applicants' submission of the web site information is noted, however, this information does not change the Examiner's position.

9. With respect to the rejection of claim 19 under 35 USC 103 over the combination of the references of Park et al. and either Qu et al. or He et al., Applicants' amendments to claim 19 and associated comments (See pages 7-9 of the response filed 6/24/05) are persuasive to overcome this rejection.

With respect to Applicants' comments that the references of Qu et al. and He et al. do not use the word "seal", the Examiner is of the position that the disclosures of these references clearly convey to one of ordinary skill in the art that the vessels are sealed during use.

10. With respect to the rejection of the claims over the combination of the references of Park et al. alone or further in view of Qu et al. or He et al. and Karube et al., Applicants argue (See pages 9-12 of the response dated 6/24/05) that it is improper to combine the references with Karube et al. because the reference of Karube et al. requires a flow of solutions.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, while the reference of Karube et al. may require a flow of solutions, the reference still discloses that the use of an array of test elements is known in the art. The primary references do not require a flow of solutions and thus one of ordinary skill in the art would have recognized that the devices of the modified primary reference can support an array of test elements for the known and expected result of simultaneously detecting for the presence of more than one analyte.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB